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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,769	07/13/2005	Gerhard Hoefle	930008-2194	5104

7590 08/20/2008
Ronald R Santucci
Frommer Lawrence & Haug
745 Fifth Avenue
New York, NY 10151

EXAMINER

KOSACK, JOSEPH R

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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08/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,769	Applicant(s) HOEFLE ET AL.	
	Examiner Joseph R. Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 and 14 is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-11, 13, and 14 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2008 has been entered.

Previous Claim Rejections - 35 USC § 103

Claims 1 and 3-11 were previously rejected under 35 U.S.C. 103(a) as being obvious over Nicolaou et al. (*Angew. Chem. Int. Ed.* 1998, 2014-2045) in view of Patani et al. (*Chem. Rev.* 1996, 3147-3176).

Applicant has supplied two executed declarations, one from Dr. Ludger Wessjohann, and one from Dr. Wolfgang Richter in support of the Applicant's position that the claims are non-obvious.

The Examiner has considered the arguments and the two declarations, and has decided to withdraw the rejection over 35 U.S.C. 103(a) because Patani et al. teaches the replacement in a chain and not in a ring system. With the teaching in Nicolaou et al. that removal or reduction of the C5 ketone resulted in a complete loss of activity and the showing made in the Richter declaration that the activity is not only maintained but

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comparable to the original epothilone, the specific change made would not have been obvious to one of skill in the art and the rejection is withdrawn.

Previous Double Patenting Rejections

Claims 1 and 3-11 were provisionally rejected in the previous action on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12 and 22 of copending Application No. 10/535,474, now published as USPN 20060128966 A1 in view of Patani et al. (*Chem. Rev.* 1996, 3147-3176).

It is noted that Applicant is considering a terminal disclaimer once the claims become otherwise allowable. As there is a maintained rejection and no terminal disclaimer yet on file. The provisional rejection is maintained. Applicant is reminded that since the instant case is the senior case, a terminal disclaimer may not be needed once all other rejections are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

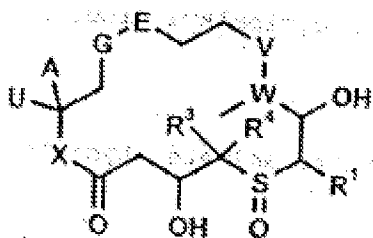
Claims 1 and 3-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for solvates in the solution phase, does not reasonably provide enablement for solvates in the isolatable or solid form. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims listed above are drawn not only to the compounds themselves, but also to solvates thereof. The current skill in the art is that the existence and physical properties of isolatable or solid form solvates is unpredictable. See Hildesheim et al., USPN 7,056,942, column 2, line 66 through column 3, line 5. Additionally, there are no examples present within the specification that teach a solid form solvate. The term solvate as defined encompasses both solution-phase and isolatable solvates (page 9 of the specification.) Therefore, on the virtue of the evidence above, it would require undue experimentation for one of skill in the art to make the solid and isolatable solvates that are claimed instantly.

Double Patenting

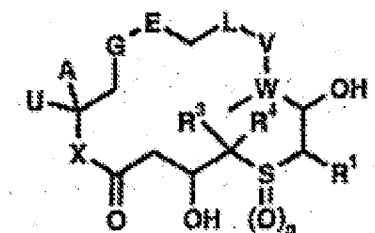
Claims 1 and 3-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12 and 22 of copending Application No. 10/535,474, now published as UPSN 20060128966 A1 in view of Patani et al. (*Chem. Rev.* 1996, 3147-3176).

The instant application is drawn to compounds of the formula:



with substitutions as defined along with a method of treating cancer with the compounds.

Determination of the scope and content of the prior art (MPEP §2141.01)



'474 teaches compounds of the formula with substitutions as defined.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

'474 does not teach a SO in place of the S or SO₂ group in the compound.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Patani et al. teach that carbonyl can be replaced by S, SO, or SO₂ if the position is not essential to the function of the molecule. See page 3167, Figure 67, Table 39, and the last paragraph of column 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to follow the synthetic scheme of '474 with the replacement suggested by Patani et al. to make the claimed invention. The motivation to do so is provided by '474. '474 teaches the use of the compounds to treat cancer. See claim 11.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Claims 1 and 3-11 are rejected. Claims 13 and 14 are currently allowable over the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Golam M. M. Shameem, Ph.D./
Primary Examiner, Art Unit 1626

/Joseph R Kosack/
Examiner, Art Unit 1626